K041954

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SEP 15 2004

Shanghai Intco Electrode Manufacturing Co.
510(k) Summary

The following information is submitted in accordance with the requirements of 21 CFR 807.92

Submitter's name: Shanghai Intco Electrode Manufacturing Co., LTD
No. 555 Hubin Road, Zhelin Town, FengXian District
Shanghai, PR China 201417
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Contact person: Don Sun, General Manager

Date Prepared: July 8, 2004

Device Name: Disposable EKG monitoring electrodes

Common/Usual Name: Monitoring Electrodes

Classification Name: Electrodes, cutaneous

Predicate devices: **Lead-Lok Inc. K832877, K911518/D**

Device Description: These Monitoring Electrodes are non-sterile, hypoallergenic, disposable, adhesive-backed with conductive centers, composed of materials commonly used in this application:

First Layer: Stainless Steel snap, that works as a connection point for the diagnostic equipment.

Second Layer: Polypropylene label substrate, used for reinforcement and a printable surface for branding.

Third Layer: Various materials i.e., medical grade polyester fabric, polyethylene foam and paper, coated with bio-compatible adhesive.

Fourth Layer: Ag/AgCl. coated, 20% carbon filled plastic sensor.

Gel Foam Layer: Polyurethane foam. Only used for conductive wet gel.

Conductive Gel: Bio-compatible conductive solid hydrogel or wet gel

Fifth Layer: Silicone coated release liner to cover the adhesive and conductive media.

The electrodes are disposable and designed for single-patient use. They have a low profile construction that uses soft pliable and conformable materials for patient comfort. Because of the adhesive nature no extra securing materials are required to anchor the device to the patient's skin. The electrodes have one universal contact point which is a stainless steel snap. The equipment manufacturers provide the receptacle to this in the form of either a snap lead wire or a pinch clip.

Technological Characteristics: Our electrodes are technologically equivalent to the predicate devices. They are physically and technically similar to those currently being marketed for ECG/EKG Cardiac monitoring, EEG brain wave monitoring, Bio-feedback and nerve sensing.

Safety and Effectiveness: Our electrodes are as safe and effective as Lead-Lok Inc. electrodes which were previously found to be substantially equivalent via 510(k) Premarket Notification K832877 and K911518/D.

The only two points of contact to the patients skin are the conductive gel and the adhesive-backed base material. Both conductive gels (wet gel and solid hydrogel), underwent the required skin sensitivity testing criteria as specified in the Tripartite Biocompatibility Guidance for Medical Devices and ISO 10993-1 requirements for skin contact. These tests include Cytotoxicity, Sensitization, and Primary Skin Irritation (test results attached). As you will see, the solid hydrogel test results mention the name Vermont Medical, Lead-Lok/Shanghai Intco acquired this formula from Vermont Medical through a technology exchange. The adhesive backed materials are purchased from outside suppliers that use medical grade adhesive and also adhere to the same test criteria (test results attached)

The effectiveness of the electrodes was determined by running tests according to AAMI standards i.e., Bias Current Tolerance, DC Offset Voltage, AC Impedance, Combined Offset and Internal Noise, Recovery Slope Time and AC Impedance after Defib. (test results attached).

For the above reasons, Shanghai Intco Electrode Manufacturing Co. considers its disposable electrodes to be as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 15 2004

Shanghai Intco Electrode Manufacturing Co. Ltd.
c/o Mr. Chris Healy
Lead-Lok Inc.
500 Airport Way
Sandpoint, ID 83864

Re: K041954
Trade Name: Disposable ECG Monitoring Electrodes
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph electrodes
Regulatory Class: Class II (two)
Product Code: DRX
Dated: September 01, 2004
Received: September 07, 2004

Dear Mr. Healy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

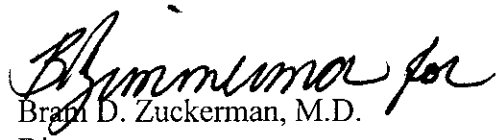
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER: K041954

DEVICE NAME: Disposable ECG/EKG (Electrocardiogram) sensing electrodes

INDICATIONS FOR USE:

These disposable noninvasive, hypoallergenic electrodes will be used as a conductive medium between the patient and the diagnostic equipment. Depending on the application, different sizes, shapes and a choice of either wet gel or solid hydrogel can be used for better results. These electrodes can be used for short-term or long-term applications, up to 3 days. This product is disposable and should only be used for single use.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR: Over-the Counter-Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041954